Amendments to the Claims:

1. (Currently Amended) A composition comprising biologically active interferon-β (IFN-β) and highly purified mannitol wherein said biologically active IFN-β has the ability to bind to IFN-β receptors and said highly purified mannitol has a reducing activity of less than 20 parts per million.

2. (Original) The composition of claim 1, wherein said composition is characterized by increased stability.

3. (Original) The composition of claim 1, wherein said composition is lyophilized.

4. (Original) The composition of claim 1, wherein said composition is a liquid.

5. (Original) The composition of claim 1, wherein said highly purified mannitol is present at a concentration of about 0.25% to about 5% by weight per volume.

6. (Previously Presented) The composition of claim 1, wherein said IFN-β is present at a concentration of 0.01 mg/ml to 15 mg/ml.

7. (Original) The composition of claim 1, wherein said formulation has a pH within a range of about pH 3.0 to about pH 9.0.

8. (Original) The composition of claim 1, also comprising human albumin.

9. (Original) The composition of claim 8, wherein said human albumin is present at a concentration of about 0.01% to about 15% by weight per volume.

10. (Currently Amended) A composition comprising biologically active interferon-β (IFN-β) and highly purified mannitol, wherein said IFN-β is recombinant human-IFN-β and has the ability to bind to IFN-β receptors, said recombinant human IFN-β is present at a concentration of about 0.01 mg/ml to about 15 mg/ml, said highly purified mannitol has a reducing activity of less than 20 parts per million and is present at a concentration of about 0.25 % to about 5% by weight per volume, the pH of the composition is about 3.0 to about 9.0, and the composition additionally comprises human albumin at a concentration of about 0.01 % to about 15% by weight per volume.

11. (Original) The composition of claim 10, wherein said composition is lyophilized.

12. (Original) The composition of claim 10, wherein said composition is a liquid or is frozen.

13. (Previously Presented) The composition of claim 10, further comprising sufficient sodium chloride to render the composition isotonic.

14. (Original) The composition of claim 13, wherein said composition is lyophilized.

15. (Original) The composition of claim 13, wherein said composition is a liquid or frozen.

16. (Currently Amended) A composition comprising biologically active interferon-β (IFN-β) and highly purified mannitol, wherein the IFN-β is recombinant human-IFN-β and has the ability to bind to IFN-β receptors, said recombinant human IFN-β is present at a concentration of about 0.05 mg/ml to about 1 mg/ml, said highly purified mannitol has a reducing activity of less than 20 parts per million and is present at a concentration of about 0.25% to about 2.5% by weight per volume, the pH of the composition is about 6.8 to about 8.2,

and the composition additionally comprises human albumin at a concentration of about 0.25% to about 2.5% by weight per volume.

17. (Original) The composition of claim 16, further comprising sufficient sodium chloride to render the composition isotonic.

18. (Original) The composition of claim 16, wherein said composition is a liquid, wherein said liquid is frozen or lyophilized.

19. (Original) The composition of claim 17, wherein said composition is a liquid, wherein said liquid is frozen or lyophilized.

20. (Currently Amended) A composition comprising biologically active interferon-β (IFN-β) and highly purified mannitol, wherein the IFN-β is recombinant human-IFN-β and has the ability to bind to IFN-β receptors, said recombinant human IFN-β is present at a concentration of about 0.25 mg/ml, said highly purified mannitol has a reducing activity of less than 20 parts per million and is present at a concentration of about 1.25% by weight per volume, the pH of the composition is about 7.3 to about 7.5, and the composition additionally comprises human albumin at a concentration of about 1.25% by weight per volume.

21. (Original) The composition of claim 20, further comprising sufficient sodium chloride to render the composition isotonic.

22. (Original) The composition of claim 20, wherein said composition is a liquid, wherein said liquid is frozen or lyophilized.

23. (Original) The composition of claim 21, wherein said composition is a liquid, wherein said liquid is frozen or lyophilized.

24. (Previously Presented) The composition of claim 1, wherein said biologically active IFN-β has the amino acid sequence set forth in SEQ ID NO:1 or SEQ ID NO:2.

25. (Original) The composition of claim 24, wherein said IFN-β is glycosylated or unglycosylated.

26. (Original) The composition of claim 1, wherein said IFN-β is recombinantly produced.

27. (Original) A pre-filled syringe comprising the composition of claim 1.

28. (Original) The pre-filled syringe of claim 27, wherein said composition is frozen.

29. (Canceled)

30. (Currently amended) A composition comprising a pharmaceutical polypeptide and highly-purified mannitol wherein said highly-purified mannitol has a reducing activity of less than 20 parts per million.

31. (Original) The composition of claim 30, wherein said pharmaceutical polypeptide is selected from the group consisting of human growth hormone, interferon, interleukin, granulocyte-macrophage colony stimulating factor, granulocyte colony stimulating factor, macrophage colony stimulating factor, beta-glucocerebrosidase, thyrotropins, etanercept, monoclonal antibodies, factor VIIa, factor VIII, urokinase, asparginase, anistreplase, and alteplase.

32. (Currently Amended) A method of producing a formulation of biologically active interferon-β (IFN-β) characterized by improved stability, said method comprising producing a formulation comprising said IFN-β and highly purified mannitol in an amount sufficient to

stabilize said IFN-β wherein said biologically active INF-β has the ability to bind to IFN-β receptors and said highly purified mannitol has a reducing activity of less than 20 parts per million.

33. (Original) A formulation made according to the method of claim 32.

34. (Currently Amended) A method of producing a formulation of biologically active interferon-β (IFN-β) having the ability to bind to IFN-β receptors, comprising the steps of:

a) removing sodium dodecyl sulfate and salts from the IFN-β by chromatography;

b) combining said IFN-β with a solution of human albumin at a pH of about 11.5 to about 12.0;

c) adjusting the pH of the solution to 7.5 with HCl; and

d) adding a solution of highly purified mannitol having a reducing activity of less than 20 parts per million.

35. (Original) A formulation produced according to the method of claim 34.

36. (Original) The method of claim 34, further comprising the step of lyophilizing the formulation.

37. (Currently Amended) A method for increasing the stability of biologically active interferon-β (IFN-β) in a pharmaceutical composition, said method comprising incorporating into said composition highly purified mannitol in an amount sufficient to stabilize said IFN-β, wherein said IFN-β has the ability to bind to IFN-β receptors and said highly purified mannitol has a reducing activity of less than 20 parts per million.

38. (Original) The method of claim 34, further comprising the step of adding sufficient sodium chloride to render the composition isotonic.

39. (Original) A formulation produced according to the method of claim 38.

40. (Original) The method of claim 38, further comprising the step of lyophilizing the formulation.

41. (Previously Presented) The composition of claim 1, wherein said biologically active IFN-β has at least 80% amino acid sequence identity with the amino acid sequence set forth in SEQ ID NO:1 as calculated using the ALIGN program with a PAM 120 weight residue table, a gap length penalty of 12, and a gap penalty of 4.

42. (Previously Presented) The composition of claim 1, wherein said highly purified mannitol has a reducing activity of less than 15 parts per million.

43. (Previously Presented) The composition of claim 1, wherein said highly purified mannitol has a reducing activity of at least 8.9 parts per million.

44. (Previously Presented) The composition of claim 2, wherein said composition contains less than 0.02 mg/ml of glucosylated IFN-β.

45. (Previously Presented) The composition of claim 44, wherein said composition contains less than 0.02 mg/ml of glucosylated IFN-β when stored at 25°C for a period of at least one month.

46. (Previously Presented) The composition of claim 45, wherein said composition contains less than 0.02 mg/ml of glucosylated IFN-β when stored at 25°C for a period of at least three months.

47. (Previously Presented) The composition of claim 44, wherein said composition contains less than 0.02 mg/ml of glucosylated IFN-β when stored at 30°C for a period of at least two months.

48. (Previously Presented) The composition of claim 47, wherein said composition contains less than 0.02 mg/ml of glucosylated IFN-β when stored at 30°C for a period of at least six months.

49. (Previously Presented) The composition of claim 48, wherein said composition contains less than 0.02 mg/ml of glucosylated IFN-β when stored at 30°C for a period of at least twelve months.

50. (Previously Presented) The composition of claim 49, wherein said composition contains less than 0.02 mg/ml of glucosylated IFN-β when stored at 30°C for a period of at least two years.

51. (Previously Presented) The composition of claim 10, wherein said biologically active IFN-β has at least 80% amino acid sequence identity with the amino acid sequence set forth in SEQ ID NO:1 as calculated using the ALIGN program with a PAM 120 weight residue table, a gap length penalty of 12, and a gap penalty of 4.

52. (Previously Presented) The composition of claim 10, wherein said highly purified mannitol has a reducing activity of less than 15 parts per million.

53. (Previously Presented) The composition of claim 10, wherein said highly purified mannitol has a reducing activity of at least 8.9 parts per million.

54. (Previously Presented) The composition of claim 10, wherein said biologically active IFN-β has the amino acid sequence set forth in SEQ ID NO:1 or SEQ ID NO:2.

55. (Previously Presented) The composition of claim 13, wherein said highly purified mannitol has a reducing activity of less than 15 parts per million.

56. (Previously Presented) The composition of claim 13, wherein said highly purified mannitol has a reducing activity of at least 8.9 parts per million.

57. (Previously Presented) The composition of claim 16, wherein said recombinantly produced IFN-β has at least 80% amino acid sequence identity with the amino acid sequence set forth in SEQ ID NO:1 as calculated using the ALIGN program with a PAM 120 weight residue table, a gap length penalty of 12, and a gap penalty of 4.

58. (Previously Presented) The composition of claim 16, wherein said highly purified mannitol has a reducing activity of less than 15 parts per million.

59. (Previously Presented) The composition of claim 16, wherein said highly purified mannitol has a reducing activity of at least 8.9 parts per million.

60. (Previously Presented) The composition of claim 20, wherein said recombinantly produced IFN-β has at least 80% amino acid sequence identity with the amino acid sequence set forth in SEQ ID NO:1 as calculated using the ALIGN program with a PAM 120 weight residue table, a gap length penalty of 12, and a gap penalty of 4.

61. (Previously Presented) The composition of claim 20, wherein said highly purified mannitol has a reducing activity of less than 15 parts per million.

62. (Previously Presented) The composition of claim 20, wherein said highly purified mannitol has a reducing activity of at least 8.9 parts per million.

63. (Previously Presented) The composition of claim 30, wherein said highly purified mannitol has a reducing activity of less than 15 parts per million.

64. (Previously Presented) The composition of claim 30, wherein said highly purified mannitol has a reducing activity of at least 8.9 parts per million.

65. (Previously Presented) The method of claim 32, wherein said formulation contains less than 0.02 mg/ml of glucosylated IFN-β.

66. (Previously Presented) The method of claim 65, wherein said formulation contains less than 0.02 mg/ml of glucosylated IFN-β when stored at 25°C for a period of at least one month.

67 (Previously Presented) The method of claim 65, wherein said formulation contains less than 0.02 mg/ml of glucosylated IFN-β when stored at 30°C for a period of at least two months.

68. (Previously Presented) The method of claim 67, wherein said formulation contains less than 0.02 mg/ml of glucosylated IFN-β when stored at 30°C for a period of at least six months.

69. (Previously Presented) The method of claim 32, wherein said biologically active IFN-β has at least 80% amino acid sequence identity with the amino acid sequence set forth in SEQ ID NO:1 as calculated using the ALIGN program with a PAM 120 weight residue table, a gap length penalty of 12, and a gap penalty of 4.

70. (Previously Presented) The method of claim 32, wherein said highly purified mannitol has a reducing activity of less than 15 parts per million.

71. (Previously Presented) The method of claim 32, wherein said highly purified mannitol has a reducing activity of at least 8.9 parts per million.

72. (Previously Presented) The method of claim 32, wherein said biologically active IFN-β has the amino acid sequence set forth in SEQ ID NO:1 or SEQ ID NO:2.

73. (Previously Presented) The method of claim 34, wherein said biologically active IFN-β has at least 80% amino acid sequence identity with the amino acid sequence set forth in SEQ ID NO:1 as calculated using the ALIGN program with a PAM 120 weight residue table, a gap length penalty of 12, and a gap penalty of 4.

74. (Previously Presented) The method of claim 34, wherein said highly purified mannitol has a reducing activity of less than 15 parts per million.

75. (Previously Presented) The method of claim 34, wherein said highly purified mannitol has a reducing activity of at least 8.9 parts per million.

76. (Previously Presented) The method of claim 37, wherein said biologically active IFN-β has at least 80% amino acid sequence identity with the amino acid sequence set forth in SEQ ID NO:1 as calculated using the ALIGN program with a PAM 120 weight residue table, a gap length penalty of 12, and a gap penalty of 4.

77. (Previously Presented) The method of claim 37, wherein said highly purified mannitol has a reducing activity of less than 15 parts per million.

78. (Previously Presented) The method of claim 37, wherein said highly purified mannitol has a reducing activity of at least 8.9 parts per million.